# This Page Is Inserted by IFW Operations and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

## IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents will not correct images, please do not report the images to the Image Problem Mailbox.

## THIS PAGE BLANK (USPTO)

Patentavdelningen

SE00/572

PUT/SE 00 / 0 0 5 7 2 2 3 -03- 2000 09/937875 REC'D 1 1 MAY 2000 **WIPO** 

PCT



Intyq Certificate

Härmed intygas att bifogade kopior överensstämmer med de handlingar som ursprungligen ingivits till Patent- och registreringsverket i nedannämnda ansökan.

This is to certify that the annexed is a true copy of the documents as originally filed with the Patent- and Registration Office in connection with the following patent application.

- Pacesetter AB, Järfälla SE (71) Sökande Applicant (s)
- (21) Patentansökningsnummer 9901194-2 Patent application number
- (86) Ingivningsdatum Date of filing

1999-03-31

### **PRIORITY DOCUMENT**

SUBMITTED OR TRANSMITTED IN COMPLIANCE WITH RULE 17.1(a) OR (b)

1999-10-12 Stockholm,

För Patent- och registreringsverket For the Patent- and Registration Office

Avgift

Fee

170:-

1

#### Technical Field

The present invention relates to a rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low.

#### 10 Background Art

15

20

25

30

35

: . . : : : The pacing rate of a rate adaptive pacemaker may become too low due to the physical demand of the patient's organism and heart. This may result in lack of oxygen supply to the myocardium. Under certain conditions the heart may not be able to fulfil the physiological needs of the patient's organism and heart if the pacing rate is not limited.

It is previously known to set a lower limit for the pacing rate. This limit value is normally determined from the patient's diagnosis and a constant or externally programmable limit can be set. Thus US-A-4,535,774 describes a stroke volume controlled pacemaker, in which the heart rate is permitted to range between prescribed minimum and maximum heart rate values. Further, in US-A-5,861,011 a pacemaker is disclosed having a system for determining the circadian rhythm by examining variations in the QT interval and adjusting the pacemaker night time setting of a lower rate limit to a lower value than the pacemaker daytime setting of the lower rate limit.

Thus, too low a pacing rate may cause too slow influx of blood enriched with oxygen. A prescribed suitable lower pacing rate limit avoids the slow influx of the fresh blood. At the same time this lower limit value should be low enough not to disturb a peaceful sleep. In that case the patient can

2 ·

feel more healthy in various everyday life conditions including peaceful sleeping.

The purpose of the present invention is to provide a rate adaptive pacemaker in which the pacing rate is prevented in a new way from becoming too low, such that the above discussed inconveniences for the patient are avoided.

#### Disclosure of the Invention

5

15

20

30

10 This purpose is obtained by a rate adaptive pacemaker according to claim 1.

Thus, by satisfying two predetermined relations the pacemaker according to the invention ensures a sufficient minimum energy supply to the patient's organism or body and at the same time the maximum value of the stroke volume is limited and these conditions are continuously automatically checked.

Preferred embodiments are set forth in the dependent claims.

According to an advantageous embodiment of the pacemaker according to the invention the first predetermined relation is

$$CO > CO_{rest}$$
 (1)

25 and said second predetermined relation is

$$(SV)/(SV_{rest}) < L$$
 (2)

where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5. In this way the actual cardiac output is ensured not to become lower than the rest state cardiac output  $CO_{rest}$  and the actual stroke volume is ensured to be less than a maximum allowed value equal to L  $\times$   $SV_{rest}$ , where L typically has a value between 1.2 and 1.5, depending on the health of the patient's myocardium. By satisfying both these conditions simultaneously a physio-

logically well founded heart work management at low work loads is ensured.

According to other advantageous embodiments of the pacemaker according to the invention the pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output ( $CO_{rest}$ ) for the patent in rest conditions, and the relation between actual stroke volume 10 (SV) and a maximum allowed stroke volume (SV $_{max}$ ) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means, and said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means 15 for comparing measured actual stroke volume SV with stroke volume  $SV_{\text{rest}}$  for the patient in rest conditions to ensure that the inequality

$$SV/SV_{rest} < L$$
 (3)

20 is satisfied and said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

25

30

: ::::

lower pacing rate limit = 
$$HR_{rest} \cdot (SV_{rest}/SV)$$
 (4)

where  $HR_{rest}$  denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied. In this way the lower pacing rate limit is continuously automatically calculated and it may also happen that the lower pacing rate limit becomes lower than the typical heart rate  $HR_{rest}$  for rest conditions of the patient.

According to still another advantageous embodiment of the pacemaker according to the invention a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac

output CO and actual stroke volume SV from the measured cardiac bioimpedance. In this way these parameters are obtained in an easy and reliable way from the time variation of the bioimpedance measured between a standard intracardiac electrode and the housing of the pacemaker, when an excitation current proceeds from the electrode tip.

#### Brief Description of the Drawings

The invention will now be described more in detail with reference to the enclosed drawings on which figure 1 is a block diagram of an embodiment chosen as an example of the pacemaker according to the invention and figure 2 illustrates the principle of bioimpedance measurements between the tip of an intracardial electrode and the metal housing of the pacemaker.

Description of a Preferred Embodiment

To avoid that the current cardiac output CO.

$$CO = SV \times HR$$
 (5)

20 becomes lower than the rest state cardiac output  ${\rm CO}_{\rm rest}$  the pacing rate must be above a lower pacing rate limit given by

lower pacing rate limit =  $(CO_{rest})/(SV)$  (6)

and since

5

10

15

25

$$CO_{rest} = HR_{rest} \times SV_{rest}$$
 (7)

lower pacing rate limit =  $(HR_{rest}) \times (SV_{rest}/SV)$  (8)

In addition thereto the maximum value of the stroke volume must be limited, i.e.

$$SV_{max} < L \times SV_{rest}$$
 (9)

#### Claims

10

25

30

35

- 1. A rate adaptive pacemaker comprising a means for determining the demand of the patient's organism, a pacing rate controlling means for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means for preventing the pacing rate from becoming too low, characterized in that said pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output (CO<sub>rest</sub>) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and maximum allowed stroke volume (SV $_{\rm max}$ ).
- 15 2. The pacemaker according to claim 1, characterized in that said first predetermined relation is

#### CO > CO<sub>rest</sub>

and said second predetermined relation is

#### $(SV)/(SV_{rest}) < L$

- where L denotes a predetermined constant > 1, preferably equal to a value between 1.2 and 1.5.
  - 3. The pacemaker according to claims 1 or 2, characterized in that said pacing rate limiting means includes a lower limit setting means for setting a lower limit value for the pacing rate, and a lower limit determining means for determining the relation between actual cardiac output (CO) and cardiac output (CO $_{\rm rest}$ ) for the patient in rest conditions and the relation between actual stroke volume (SV) and a maximum allowed stroke volume (SV $_{\rm max}$ ) and calculating a lower pacing rate limit value from said relations for supply to said limit setting means.
    - 4. The pacemaker according to claim 3, characterized in that said lower limit determining means includes a stroke volume measuring means for measuring actual stroke volume SV and comparison means for comparing measured actual stroke

volume SV with stroke volume  $SV_{\text{rest}}$  for the patient in rest conditions to ensure that the inequality

#### $SV/SV_{rest} < L$

10

15

is satisfied, and in that said lower limit determining means is adapted to calculate a lower pacing rate limit value from the equation

lower pacing rate limit =  $HR_{rest} \cdot (SV_{rest}/SV)$ 

where  $HR_{rest}$  denotes the heart rate for the patient in rest conditions, provided that said inequality is satisfied.

- 5. The pacemaker according to any of the claims 2 4, characterized in that a bioimpedance measurement unit is provided to measure the cardiac bioimpedance as a function of time for determining therefrom actual cardiac output (CO) and actual stroke volume (SV) from the measured cardiac bioimpedance.
- 6. The pacemaker according to any of the claims 2 4, characterized in that an ECG measuring and analyzing unit is provided to measure ECG and determine therefrom actual cardiac output (CO) and actual stroke volume (SV).

9

Abstract

A rate adaptive pacemaker comprises a means (2) for determining the demand of the patient's organism, a pacing rate controlling means (16) for controlling the pacing rate in response to the patient's demand, and a pacing rate limiting means (20) for preventing the pacing rate from becoming too low. The pacing rate limiting means is adapted to limit the pacing rate downwards such that a first predetermined relation is satisfied between actual cardiac output (CO) and cardiac output (COrest) for the patient in rest conditions and a second predetermined relation is satisfied between actual stroke volume (SV) and maximum allowed stroke volume (SV $_{\rm max}$ ).

15

10

5

Figure 1

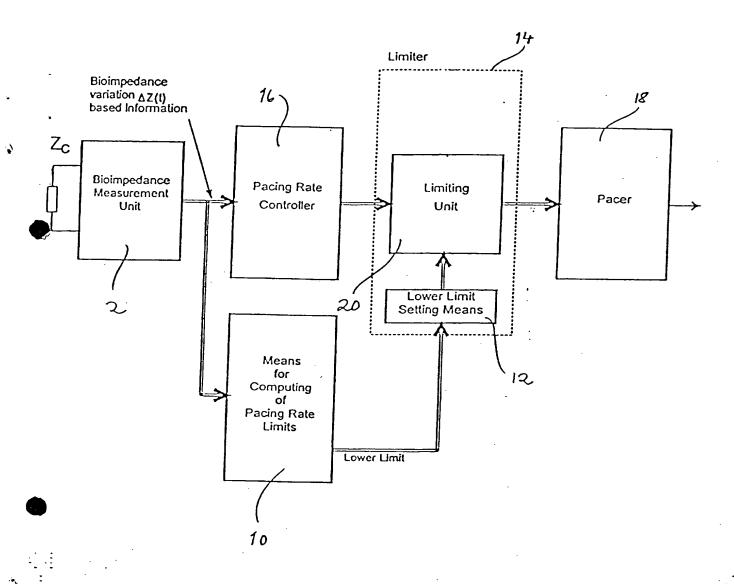


Fig.

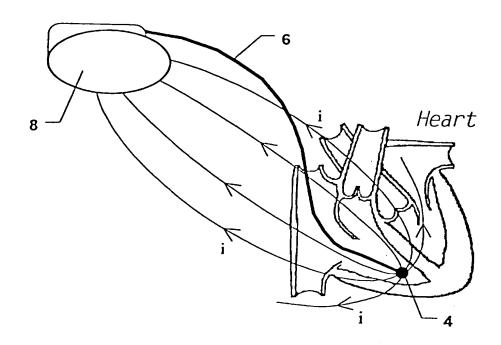


Fig. 2



Creation date: 03-22-2004

Indexing Officer: JCOBB - JALESHA COBB

Team: OIPEBackFileIndexing

Dossier: 09937875

Legal Date: 01-30-2002

No.	Doccode	Number of pages
1	FOR	38
2	FOR	24

Remarks:

Order of re-scan issued on .....